K080034

SECTION 03: 510(k) SUMMARY (807.92c)

JUN 17 2008

510(k) Summary

Three Stage Venous Return Cannula

Submitter Information

This Premarket Notification is submitted by:

Terumo Cardiovascular Systems Corporation
6200 Jackson Road
Ann Arbor, Michigan 48103

Contact: Andrea N. Wallen
Telephone: 1-800-262-3304, Ext. 6395
Fax: 734-741-6030
Date: January 3, 2008

Device Name

Trade Name: Three Stage Venous Return Cannula
Common Name: Venous Cannula
Classification Name: CPB vascular catheters, cannulae, or tubing are classified as Class II devices per 21 CFR § 870.4210.

Predicate Device

The unmodified predicate device is identified as Terumo's current line of Dual Stage Venous Return Cannulae, which fall under 510(k) # K810415.

Device Description

The Three Stage Venous Return Cannula consists of a single tube body with a 3/8" flared end to allow for connection to the bypass circuit. These cannulae have three open areas for venous drainage. An obturator is included. Its purpose is to decrease blood loss during insertion. Insertion depth markers are printed on each cannula and aid in positioning the cannula.

Intended Use

These cannulae are indicated for single-tube venous drainage from the right atrium and vena cava during cardiopulmonary bypass surgery. These devices are indicated for up to 6 hours of use.

Technological Characteristics

The Three Stage Venous Return Cannula is used in open heart surgery. During open heart surgery, blood is drained into a venous cannula upstream of the heart at the superior/ inferior vena cava and right atrium. The cannula is connected to tubing that routes the blood to a heart/ lung machine where the blood is pumped and oxygenated. The blood then continues through this perfusion circuit back to

the outlet side of the heart (the patient's aorta), where the blood re-enters the patient's circulatory system via an arterial cannulae.

There are three major differences between the modified and unmodified devices.

- The distal portion of the three stage spring reinforced body maintains a single outside diameter to allow for a smaller incision site, whereas the dual stage cannula has a step-up in the outer diameter.

- The (unmodified) dual stage device has a ½" connection site, whereas the (modified) three stage device has a 3/8" connection site which allows for a smaller blood volume to prime the bypass circuit.

- The modified device includes a third basket which has been added to allow the smaller diameter to maintain comparable flow characteristics to the dual stage venous return cannulae.

Performance Evaluation

Comparison studies of the performance specifications of the Three Stage Venous Return Cannula and the unmodified predicate Dual Stage Venous Return Cannula have been conducted and have shown to be substantially equivalent to the predicate (unmodified) Dual Stage Venous Return Cannula. These tests include:

- Connector attachment
- Clamp test
- Obturator Seal Test
- Kink test
- Collapse test
- Tensile test
- Flow Testing
- Simulated use test

Conclusion

In summary, the Three Stage Venous Return Cannula performed as intended and is substantially equivalent in intended use, principles of operation, technology, design, materials, and performance to the predicate (unmodified) Dual Stage Venous Return Cannula. Any noted differences between the devices do not raise new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2008

Terumo Cardiovascular Systems Corporation
c/o Ms. Andrea Wallen
Specialist, Regulatory Management
6200 Jackson Road
Ann Arbor, MI 48103

Re: K080034
Three Stage Venous Return Cannula, Model 816460
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary bypass vascular catheters, cannula, or tubing
Regulatory Class: Class II (two)
Product Code: DWF
Dated: April 7, 2008
Received: April 8, 2008

Dear Ms. Wallen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vochmes

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K080034

Device Name: Three Stage Venous Return Cannula

Indications For Use:

These cannulae are indicated for single-tube venous drainage from the right atrium and vena cava during cardiopulmonary bypass surgery. These devices are indicated for up to 6 hours of use.

Andrea N. Wallen
Regulatory Affairs Specialist
Terumo Cardiovascular Systems

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K080034